

REMARKS

With entry of this amendment, claims 1, 5, 8-35, 42-50, 52, and 64-111 will be pending. Claims 68-111 have been added. Claims 2-4, 6, 7, 36-41, 51, and 53-59 have been canceled without prejudice. Claims 1, 5, 35, and 43-50 have been amended. Claims 13-34 and 64-67 have been previously deemed allowable. The Applicants wish to thank the Examiner for the allowance of these claims.

Claim Rejections – Informalities

Claims 1, 5-12, 35, 42-50, 52, 58, and 59 were rejected due to various claim informalities. Independent claim 1 has been amended to recite a method of monitoring the presence of one or more chromophores in a sample of biological tissue, which method comprises illuminating an area of such tissue sample by projecting light from a light source, receiving light remitted by the illuminated area of tissue at a photo-receptor, spectroscopically analyzing the light projected from the light source and the remitted light received by the photo-receptor and utilizing said analysis to generate data indicative of differences between light projected from the light source and the remitted light, using the generated data to define a parameter of the tissue, processing the generated data using a predictive mathematical model of the optical properties of the biological tissue to normalize the defined parameter defined by the generated data to a standard value of that parameter, and measuring at least one further parameter of the tissue using said processed data processed to normalize the defined parameter defined by the generated data to a standard value.

Independent claims 5 and 35 have been similarly amended. The Applicants respectfully submit that these amendments to independent claims 1, 5, and 35 overcome the Examiner's objections based upon informalities in the claim. Claims 6-12, 42-50, and 52 depend from claims 1, 5, and 35, respectively, and are thus allowable for the reasons discussed with respect to claims 1, 5, and 35. Claims 43-47, 49, and 50 have been amended to replace the "means for" language with reference to the language of claim 35 for clarity. Further, claim 48 has been amended to depend from claim 35, correcting a typographical error pointed out by the Examiner. Claims 58 and 59 have been canceled by this amendment.

Claim Rejections - §112

Claims 1, 5-12, 35, 42-50, and 52 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner contends that the specification “fails to disclose comparing variations in the intensity and spectral characteristics of the normalized data with data representing a sample of characteristics of light remitted by a sample of known structure.” See the Office action of 7/06/04, page 2, paragraph 3. The Applicants respectfully submit that claims 1, 5-12, 35, 42-50, and 52 as amended are supported by the specification as originally filed, as is set forth below.

Support for claim 1 can be found, among other places, on page 41, lines 13 to 21, herein referred to as paragraph P, which reads as follows:

The present invention includes any method of analyzing biological tissue comprising illuminating the tissue with light, spectrally measuring and analyzing the differences between the incident and remitted light, the analysis of this data to define a parameter of the tissue, the normalization of the data to a standard value of that parameter using a predictive mathematical model of the optical properties of the biological tissue, and the subsequent measurement of a further parameter from that normalized data, preferably with more than one sequential normalization and analysis step to define further parameters.

Line 3 of claim 1 recites “illuminating an area of such tissue sample by projecting light from a light source.” One of skill in the art would understand that this step comprises ‘illuminating the tissue with light’ as in line 2 of Paragraph P.

Line 4 of claim 1 recites “receiving light remitted by the illuminated area of tissue at a photo-receptor.” One of skill in the art would understand that in order to spectrally measure and analyze the differences between the incident and remitted light, the light remitted would be received at a photo-receptor.

Lines 6 to the end of claim 1 find support in the disclosure of paragraph P and closely follow the language of that paragraph. Consequently, the Applicants respectfully submit that the subject matter of claim 1 is described in the specification, and that independent claim 1 is allowable.

Independent claims 5 and 35 have amended in a similar manner. Support for the amendments to these claims can be found, among other places, in paragraph P for the same and similar reasons as set forth above. Consequently, the Applicants respectfully submit that independent claims 5 and 35, and dependent claims 6-12, 42-50, and 52, respectively, are allowable.

Withdrawal of the 112 rejection of claims 1, 5-12, 35, 42-50, and 52 is respectfully requested.

Claim Rejections - §103

Claims 58 and 59 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gutkowicz-Krusin, et al in view of Thomas, et al. Claims 58 and 59 are canceled by this amendment.

New Claims

New claims 68-106 correspond to the claims allowed in the corresponding UK patent derived from PCT/GB00/02124. New independent claims 68 and 95 are directed towards method and apparatus in which a tissue sample is illuminated and spectroscopic analysis of the projected and illuminated light is utilized to identify the presence of one or more identified chromophores in a tissue sample. The presence of the chromophores is accomplished by comparing obtained spectroscopic analysis of the projected and remitted light with records of spectral characteristics of remitted light remitted by reference samples of known structure and outputting an identification of the chromophores associated with the record identifying spectral characteristics mostly closely corresponding to the obtained spectroscopic analysis of the projected and remitted light. Basis for the claimed apparatus may be found in the current specification between page 46, line 8 and page 52, line 3. Specific basis for comparing spectral characteristics of remitted light with records of the spectral characteristics of light remitted by tissue samples of known structure may be found at, for example, page 7, lines 9-12, page 9, lines 18-23, and page 23, line 10-page 25, line 13 (in particular page 24, line 23-page 25, line 10). Basis for new claims 68-106 may also be found in claims 1-12 and 35-52 as originally filed.

Further, none of the prior art cited by the Examiner teaches or suggests an apparatus for monitoring the presence of individual chromophores in a tissue sample, said apparatus comprising a light source operable to illuminate an area of a tissue sample with different wavelengths of light, a photo-receptor arranged to receive light remitted by an area of a tissue sample illuminated by said light source, and a spectroscopic analyzer operable to utilize the spectral characteristics of remitted light received by said photo-receptor and the spectral characteristics of light projected by said light source to identify the presence of said one or more chromophores within the area of the illuminated tissue sample from which remitted light is received by said photo-receptor, wherein said spectroscopic analyzer comprises records of the spectral characteristics of light remitted by reference samples of tissue of known structure containing identified chromophores, said spectroscopic analyzer being arranged to compare the spectral characteristics of remitted light received by said photo-receptor with said records to identify the record including spectral characteristics most closely matching the characteristics of said remitted light received by said photo-receptor and to output as an identification of individual chromophores present in the area of the illuminated tissue sample from which remitted light is received by said photo-receptor an identification of the chromophores associated with said spectral characteristics by said record, as is recited in claim 68.

Further, none of the prior art cited by the Examiner teaches or suggests a method of monitoring the presence of individual chromophores in a sample of tissue, comprising storing records of the spectral characteristics of light remitted by reference samples of tissue of known structure containing identified chromophores, illuminating an area of a tissue sample with different wavelengths of light using a light source, receiving light remitted by the illuminated area of tissue at a photo-receptor, comparing the spectral characteristics of remitted light received by said photo-receptor with said records to identify the record including spectral characteristics most closely matching the characteristics of said remitted light received by said photo-receptor, and outputting as an identification of the individual chromophores present in the area of the illuminated tissue sample from which remitted light is received by said photo-receptor an identification of the chromophores associated with said spectral characteristics by said record, as recited in claim 95.

Claims 69-94 depend from independent claim 68, and claims 96-106 depend from independent claim 95. For the reasons discussed above, as well as for other reasons not discussed herein, the Applicants respectfully submit that new claims 68-106 are allowable.

New claims 107 and 109 depend from claims 1 and 5, respectively, and refer to the further processing of normalized data to identify a further parameter of a tissue sample. Support for these claims may be found, among other places, on page 41, lines 20 and 21. Claim 108 depends from claim 1 and refers to the defined parameter for which data is renormalized as being papillary dermis thickness. Support for this claim may be found, among other places, on page 25, lines 19 and 20.

New claim 110 is an independent claim referring to both normalization for papillary dermis thickness and determining the presence and/or depth and/or concentration of one or more chromophores. Dependent claim 111 specifies a number of chromophores. Support for these claims may be found, among other places, on page 25, lines 19 and 20, page 41, lines 13-21, and page 10, lines 3-5.

CONCLUSION

In view of the foregoing, reconsideration and allowance of claims 1, 5, 8-12, 35, 42-50, 52, and 68-111, in addition to the previous allowance of claims 13-34 and 64-67, are respectfully requested. Should any issues remain that preclude the allowance of the application, the Examiner is strongly encouraged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Gregory J. Hartwig', with a large, stylized flourish extending from the end of the signature.

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